AD-A147 257 MILITARY VITAL SIGN MONITOR(U) NAVAL OCEAN SYSTEMS CENTER SAN DIEGO CA R W KATAOKA ET AL. 30 SEP 84 NOSC/TR-992 1/1

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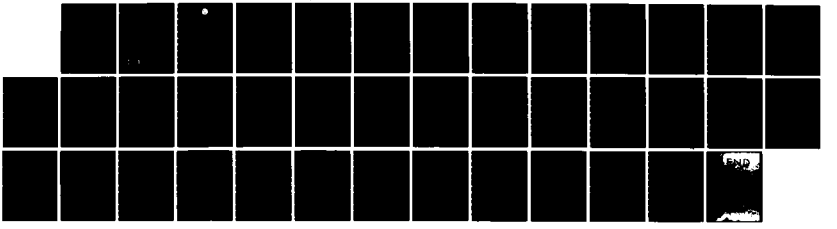

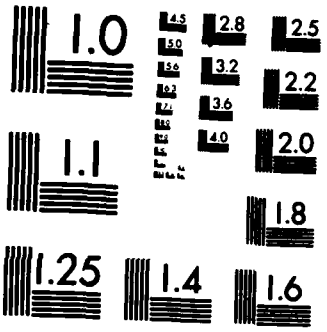
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Technical Report 992

MILITARY VITAL SIGN MONITOR

R. W. Kataoka
F. R. Borkat
Marine Sciences and Technology Department
Code 514

30 September 1984
Final Report
February 1984 — July 1984

Prepared for
Naval Medical Research & Development Command
Code 45

NOSC

NAVAL OCEAN SYSTEMS CENTER
San Diego, California 92152

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NAVAL OCEAN SYSTEMS CENTER SAN DIEGO, CA 92152

AN ACTIVITY OF THE NAVAL MATERIAL COMMAND

F. M. PESTORIUS, CAPT, USN
Commander

R.M. HILLYER
Technical Director

ADMINISTRATIVE INFORMATION

This technical report describes work performed under program element number 64771N, Work Unit Number MO993.001-0006 (NOSC 514-CN10), between 15 February and 30 July 1984 for the Naval Medical Research and Development Command, Code 45, Bethesda, MD 20014. It summarizes the investigation of commercial vital monitoring devices for use aboard Navy/Marine Corps helicopters. It also presents Army and Air Force activity in that area, as well as NATO requirements. In addition, generalized military testing procedures are identified for medical equipment used aboard aircraft. This work was performed by R. W. Kataoka (Code 514) with the assistance of F. R. Borkat (Code 514) under the direction of L. Bivens, Head, Biological Sciences Branch (Code 514).

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ACKNOWLEDGEMENTS

The authors wish to express their sincere appreciation for the valuable assistance and contributions provided by the following people:

V. Coulter, LT, USAF, USAF School of Aerospace Medicine, Brooks AFB, TX
D. Sears, Environmental Branch, USAF School of Aerospace Medicine, Brooks AFB, TX
J. Duffman, Sgt, USAF, USAF School of Aerospace Medicine, Brooks AFB, TX
L. Warfel, SSgt, USAF, USAF School of Aerospace Medicine, Brooks AFB, TX
L. Sherman, Armed Forces Medical Intelligence Center, Ft. Detrick, Frederick, MD
J. Walker, Armed Forces Medical Intelligence Center, Ft. Detrick, Frederick, MD
C. Thayer, US Army Medical Bioengineering Research and Development Laboratory, Ft. Detrick, Frederick, MD
L. Wylie, US Army Academy of Health Sciences, Ft. Sam Houston, TX
P. Moomjean, UCSD Emergency Medical Service, San Diego, CA
G. Samaras, GMS Engineering, Columbia, MD
E. Postow, NMRDC, Bethesda, MD

RB

UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

1a. REPORT SECURITY CLASSIFICATION UNCLASSIFIED	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF REPORT Approved for public release; distribution unlimited.
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S) NOSC TR 992	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION Naval Ocean Systems Center 6b. OFFICE SYMBOL (if applicable) Code 514	7a. NAME OF MONITORING ORGANIZATION
6c. ADDRESS (City, State and ZIP Code) San Diego, CA 92152	7b. ADDRESS (City, State and ZIP Code)
8a. NAME OF FUNDING/SPONSORING ORGANIZATION Naval Medical Research and Development Command 8b. OFFICE SYMBOL (if applicable) Code 45	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
8c. ADDRESS (City, State and ZIP Code) Bethesda, MD 20014	10. SOURCE OF FUNDING NUMBERS PROGRAM ELEMENT NO. 64771N; PROJECT NO; TASK NO. MO933; WORK UNIT NO. 514-CN10

11. TITLE (include Security Classification)
MILITARY VITAL SIGN MONITOR

12. PERSONAL AUTHOR(S)
R. W. Kataoka and F. R. Borkat

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Final	FROM Feb 84 TO Jul 84	30 September 1984	35

16. SUPPLEMENTARY NOTATION

17. COSATI CODES			18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
FIELD	GROUP	SUB-GROUP	Medical equipment Monitoring devices Vital signs

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

The investigation of commercial vital monitoring devices for use aboard Navy/Marine Corps helicopters is summarized. Army and Air Force activity in test area, as well as NATO requirements, are presented. Finally, generalized military testing procedures are identified for medical equipment used aboard aircraft.

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT	21. ABSTRACT SECURITY CLASSIFICATION	
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT ☐ DTIC USERS	UNCLASSIFIED	Agency Accession
22a. NAME OF RESPONSIBLE INDIVIDUAL R. W. Kataoka	22b. TELEPHONE (include Area Code) (619) 225-6542	22c. OFFICE SYMBOL Code 514

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83 APR EDITION MAY BE USED UNTIL EXHAUSTED
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OBJECTIVE

1. Test and evaluate commercially available devices that monitor patient vital signs of blood pressure and pulse in the operating evvironment of a Navy or Marine Corps medical evacuation helicopter.

2. Develop methods for determining the safety and effectiveness of all medical equipment used during Navy operations to assure that the equipment is compatible with Air Force, Army, and NATO practices.

RESULTS

1. Studies were conducted which examined the activities of Army, Air Force, Navy, NATO and Israel in the development and testing of vital sign monitors adaptable to use aboard aircraft.

2. The Medtek BPI 420 Blood Pressure Instrument is approved for vital sign monitoring aboard a helicopter.

3. Air Force testing currently in progress may result in approval of the LIfestat Model 100 (Physio Control, Redmond, WA) and the Omega 5000 (Invivo Research Laboratory, Broken Arrow, OK).

4. Interservice Memoranda of Agreement are active between Army, Navy, and Air Force to expedite testing of various systems economically and for the general use of all services.

RECOMMENDATIONS

1. Provide the Air Force list of equipment currently approved for fixed wing aircraft and helicopters, as well as updates, to all potential land and sea units which may participate in medical evacuations. For the safety of the patient and the crew, limit use of medical equipment to the approved items.

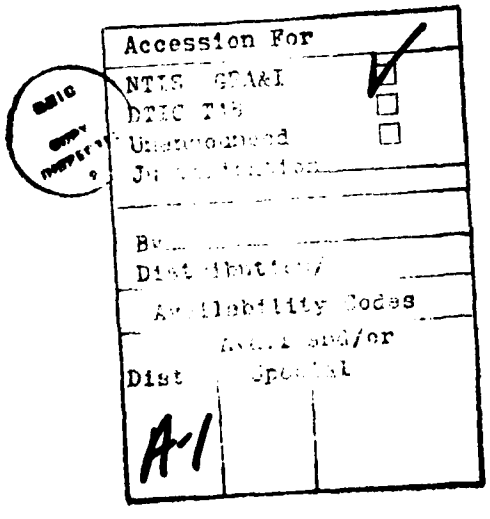
2. Establish a training program or include a section in the Corps school that covers aeromedical evacuation. The training should be compatible with the NATO instruction and qualification. Special circumstances covered should include problems that can arise from measurement and treatment at altitude variations and in noise and vibration. Much can be learned from the Army air ambulance service, the Military Assistance to Safety and Traffic (MAST) program, and civilian lifeflight and air ambulances.

3. Continue to use the Memorandum of Agreement with the Air Force for testing medical equipment for aircraft use. Establish a supplemental facility or procedure for additional tests for shipboard use when not covered by the Air Force test and evaluation procedures.

4. Screen all equipment purchased by the Navy for possible use on aircraft or aboard ship against the approved list and in compliance with the environmental test standards. Inform all potential suppliers of these requirements so that they may include these considerations in their manufacturing process.

5. Revise Authorized Medical Allowance List (AMAL) to indicate fixed wing and helicopter approved equipment. Label all equipment approved for aeromedical evacuation. Phase out all equipment not meeting environmental test standards for shipboard use.

6. Inform all medical equipment users of the publication, Health Devices, by Emergency Care Research Institute.



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INTRODUCTION

BACKGROUND

Care of the combat casualty is very important for all military operations. The proper level of care administered in a timely manner may determine whether the casualty will survive or how quickly he will be returned to active status. One of the elements of casualty treatment is transport between care facilities. Generally, transport means a break in the continuity of patient care because instrumentation for measuring necessary vital signs does not provide reliable readings in most transport vehicles. The Navy and Marine Corps, recognizing that transport is an interruption of care, use the helicopter for the major casualty transport vehicle because it imposes the shortest break in care.

During the Naval Medical Research and Development Command (NMRDC) briefing to the Director of Naval Medicine in November 1983, it was recognized that no effort has been made to identify commercial medical equipment which could monitor patient vital signs under field conditions. Specifically, due to the break in casualty care even using helicopter transport, a clear need was stated for a device which would monitor blood pressure and pulse in the high noise and vibration environment of the Navy and Marine Corps helicopters used for medical evacuation.

With this requirement, the Naval Ocean Systems Center (NOSC) was requested by NMRDC to prepare a research plan for test and evaluation of appropriate commercial vital monitor equipment for use aboard Navy and Marine Corps helicopters. The plan was approved and the project was begun in February 1984.

OBJECTIVES

The initial objective of this study was to test and evaluate commercially available devices that monitor patient vital signs of blood pressure and pulse in the operating environment of a Navy or Marine Corps medical evacuation helicopter. A secondary objective identified during the study was to develop methods for determining the safety and effectiveness of all medical equipment used during Navy operations and to assure that the equipment is compatible with Air Force, Army and NATO practices.

SCOPE

A survey was made of current commercial blood pressure and heart rate measurement devices. The Air Force and the Army were consulted for their current efforts and practices with respect to vital sign monitoring in aeromedical evacuation. Since only one of the commercial devices had been approved for helicopter use by any of the services, two other likely candidates were selected for testing. The tests are being performed at the Air Force School of Aerospace Medicine through a Memorandum of Understanding with the Navy.

COMMERCIAL BLOOD PRESSURE MEASUREMENT DEVICES

CURRENT TECHNIQUES BEING USED ON AIRCRAFT

Three techniques are used for the measurement of blood pressure aboard aircraft: the auscultatory, ultrasonic, and oscillometric. All three measure systolic and diastolic blood pressure. The oscillometric technique also measures mean pressure. All three techniques can be used to measure heart rate along with blood pressure. All three can be initiated automatically or manually, but only the first two can be measured manually. The oscillometric technique requiries electronic processing assistance, usually in the form of a microprocessor. There are commercial examples of all three that work aboard fixed wing aircraft, but only the oscillometric technique has been used with success aboard a helicopter, and then only with careful attention to technique.

In the auscultatory technique using modern instruments, a conventional sphygmomanometer cuff is inflated to above anticipated systolic pressure. The cuff is automically allowed to deflate at a prescribed rate. The appearance and disappearance of sounds as the cuff pressure passes systolic and diastolic pressure are detected on the arm by the instrument, and these points are registered on some form of display, usually digital. Because this technique relies on sound, it is not reliable in the noisy environment of a helicopter, and no acceptable devices have been identified using it.

The ultrasound technique uses the same inflation and deflation scheme, but instead of sensing sound, an ultrasonic motion detector senses wall motion under the cuff. As the pressure in the cuff drops, systolic pressure is that cuff pressure when the wall first starts to move, while diastolic pressure is that pressure at which major wall motions cease. Again, a digital display is usually used. And, like the auscultatory technique, the technique is not reliable in the environment of the helicopter.

The oscillometric technique uses the same inflation and deflation scheme as the other two, but differs in that it senses pressure within the cuff, rather than sensing something on the body. The entire time course of the waveform of the cuff pressure is considered. An inflated cuff wrapped tightly around a limb shows pressure oscillations transmitted from the encircled arteries. The oscillations are at a maximum at mean arterial pressure. Because this value is easily detected, it is presented on most displays. Most physicians are trained using the Riva-Rocci Method with Korotkoff sounds, which identifies systolic and diastolic pressure only. As a result, mean pressure does not have the understood clinical significance as do systolic and diastolic pressure, and its value in patient management may not clear. The amplitude characteristics of the waveform change at systolic and diastolic pressure. These three charac-

teristics are recognized by a microprocessor in the instruments that use the oscillometric technique. The quality of the measurement produced, particularly in a noisy and vibrating environment like that of a helicopter, depends on a program that searches the waveform sensed. As a result, some devices perform better in a helicopter than do others.

SURVEY OF MANUFACTURERS AND COMMERCIAL TEST INFORMATION

A comparative survey of the current vital sign monitors with their important features is presented in appendix A.

Commercial testing generally covers operating and storage temperature ranges and humidity. Since blood pressure measurement devices rely on air pressure, occasionally the manufacturer will cite an altitude range. The temperature range for operation is generally between 50°F and 110°F for operation and 0°F and 125°F for storage. The humidity range is generally between 10 and 60 to 90% relative, non-condensing. Operating altitude range is quoted as up to 10,000 ft. No formal test results on the operating environment of noise or vibration for any of the instruments is provided by any of the manufacturers.

RECENT MILITARY TESTS OF VITAL SIGN MONITORING DEVICES

ARMY TEST ON M113 ARMORED PERSONNEL CARRIER

The Army anticipates that the major transport for casualties will be the M113 Armored Pesonnel Carrier (APC). This vehicle has an even higher noise and vibration level than does any helicopter. The noise intensity in the crew compartment has been measured as high as 125 decibels, and the pitch and vibration is severe. The lighting is poor and there is very little room for the aidman to work. The Army is concerned about vital sign monitoring in the M113 APC, and has conducted extensive testing of devices aboard it. It can probably be assumed that any measurement device that works in the M113 will also work in a Navy or Marine Corps helicopter. The Army has also contracted for development of vital sign monitors specifically for use aboard the M113.

In the report issued by the US Army Medical Bioengineering Research and Development Laboratory in April, 1982 (Carl R. Thayer, "Vital Signs Monitors Tested in the M113 Armored Personnel Carrier," Memorandum Report No 3-82), they presented results of tests on seven blood pressure measurement devices that represented the three basic methods of measurement described earlier. The manufacturers of these devices are listed in appendix B. They also reported on three monitors that measured pulse alone. All the heart rate monitors used the fingertip optical plethysmograph method. In their tests at the Aberdeen Proving Ground, they performed measurements inside the APC while it traveled on a paved track and on a cross-country course.

None of the devices for either blood pressure measurement or pulse measurement performed on the cross-country course. The Biomega 423A did produce good readings when the APC was on the paved track, but only after isolating the control unit from vibrations by placing it on the patient's chest on a folded blanket.

None of the pulse rate monitors performed well to the satisfaction of the Army, particularly after noting that the plethysmograph technique relies on blood flow to the extremities, which probably would be reduced in casualties in some state of shock.

In the concluding remarks of the report, it is stated that "... the need for this information should be reassessed. A patient's vital signs are clearly important only if the medical practitioner is in a position to exert some beneficial influence over them." This implies that the medical personnel must have both the training and the tools to effectively intervene in crisis during transport.

The report also also suggests that new methods for blood pressure monitoring be developed and that this be coupled with the new and even more restrictive task of measuring vital signs through chemical protective clothing.

The Army currently has four contracts for the development of special

purpose vital sign monitoring equipment. Most of the devices are not ready for testing and will be discussed in a later section. One instrument, however -- that built by GMS Engineering of Columbia, MD -- was observed in its prototype testing at the Aberdeen Proving Grounds in March 1984.

The GMS Engineering uses a modified oscillometric technique using two sphygmomanometer cuffs. The test was performed on a well person wearing a shirt and medium jacket simulating chemical protective clothing. One cuff was placed on the upper arm, and the other with the sensor was placed on the forearm. The test patient was lying on a foam pad, and the GMS instrument was placed in a foam filled box. Consistent readings were obtained on the patient when the APC was on the paved test track. Readings were also obtained during the run on the cross-country test.

During the tests, no independent method was used to measure blood pressure. The heart rate was checked by simple palpation, but this worked only at low speed on the paved track. Training and diligence are necessary for proper placement of the cuffs over the clothing of the subject. Only one normal subject was used during the test, and it was not obvious how well the GMS Engineering prototype would work on a patient with below normal blood pressure. It is felt that if the monitor works on the APC, it will work on any helicopter.

ISRAELI MILITARY UNIT

The Israel Defense Force has objectives for medical evacuation that are similar to those of the Navy and Marine Corps. They have no helicopters dedicated to medical purposes, so any life support equipment must be rapidly transportable into a general utility helicopter. As a result, they have developed some equipment that is reported to provide all the necessary monitoring and life support funtions found in a well equipped trauma ambulance, including blood pressure and heart rate measurement. Unfortunately, at this time the Israelis are planning to develop the unit commercially and, in order to protect commercial rights, are not publishing details of either its design or its capabilities. Direct contact with the Israel Embassy has not produced any specific information.

First hand observation by three US military observers and one civilian observer as well as consultation with the Armed Forces Medical Intelligence Center, has indicated the following: The unit is 3 to 4 ft high and 2 to 3 ft wide. It is less than 1 foot deep. It mounts to the helicopter near the transmission housing, and contains a defibrillator-monitor, a suction unit, and compressed oxygen. These devices appeared to be of standard commercial manufacture. No blood pressure measurement unit was noticed, but this does not exclude there being one. The entire unit is not light in weight.

MILITARY CONTRACTS FOR DEVELOPMENT OF VITAL SIGN MONITORING RELATED EQUIPMENT

GENERAL

The military has released a number of contracts related to vital sign monitoring. These contracts are for equipment that accounts for some of the special conditions expected during battle, and are not for conditions normally encountered in emergency medicine. Thus, manufacturers do not normally market for this setting. The Navy has awarded one contract, the Air Force one contract, and the Army four contracts. Except for the prototype from GMS Engineering tested by the Army at the Aberdeen Proving Grounds, none of the contracts has resulted in a production unit. A description of each of the contracts shows that even if none of the commercial devices for vital sign monitoring works now, equipment specifically designed for this task, although expensive, should be available within a few years.

NAVY

The Navy contract, Number N00014-82-C-0454, entitled "Short Distance Life Detection System," was awarded to Michigan State University. It uses portable, hand carried, microwave generators and detectors to measure changes in electromagnetic field. The device is to be capable of detecting heart beat and breathing movements of a casualty through biological and chemical warfare protective clothing. It is also projected that the device will provide an accurate reading of heart rate. A prototype has worked on a stationary subject, but the monitoring device did not work when it was tested for operation in a high vibration environment at the Aberdeen Proving Ground. The detection scheme is being reworked in consideration of the problem.

AIR FORCE

The Air Force contract, Number F33615-84-C-0654, entitled "Improved Vital Signs Monitor (VSM)" was awarded to the University of Denver under the chemical defense program. The program was initially for measurement on a patient wearing a chemical warfare suit or chemical casualty bag, and has been expanded to require that the unit work under all weather conditions in a high noise and vibration environment, and that it also measure respiratory rate. The device to be built will use the auscultatory method for blood pressure measurement, will be battery powered for measurements, but will use a hand inflation of the cuff. Ten prototypes with documentation are expected before the end of FY 85.

ARMY

There has been some coordination between the Air Force and the Army on the vital signs monitoring problem to the extent that each service is developing its own units but with different techniques. The Air Force is

using the auscultatory technique, while the Army is using the oscillometric technique for their development. The Army has the most extensive program of special contracts for vital sign monitoring equipment with four: two for monitors of blood pressure and heart rate, and two for heart rate alone.

The contract in response to solicitation No. DAMD 17-82-Q-0013 is being worked on by two contractors. It calls for the building of a battery powered device for measuring blood pressure and heart rate, at a minimum, through chemical protective dress or a protective wrap and which does not violate the integrity of the covering. In this solicitation, the device need not operate in the high noise and vibration environment like the M113. The solicitation also calls out operator interfacing, contamination resistance requirements, and other less harsh environmental considerations.

The GMS Engineering contract described earlier, No. DAMD 17-83-C-3064, is one of the more ambitious. The initial description was that the GMS vital sign monitor will provide blood pressure, heart rate, respiration rate, and tidal volume measurements through chemical warfare protective clothing. The double bladder technique tested in the prototype version describe earlier was used. Six prototypes are expected.

The second contract, No. DAMD 17-83-C-3072, is with Titan Systems, Inc., San Diego, CA. The instrument uses the streaming potential technique, a method which is normally not used for blood pressure measurement. This technique relies on the electrons in flowing blood generating a measureable voltage outside the blood stream. The voltage can be correlated with pressure, but is not an exact measure. This technique is supposed to work in the high noise and vibration environment of the Army M113, but no tests have yet been made. Up to this time, a pulse rate measure has been developed, with the blood pressure, respiration rate, and tidal volume measures to be developed.

The contract in response to solicitation DAMD 17-82-C-0012 is being worked on by an additional two companies. This solicitation requires the building of a battery powered heart rate monitor alone, the primary function of which is the detection of life in a chemical warfare environment. This device not only must operate through a protective covering, but it must also operate in a helicopter and in the M113.

The first of these two, contract No. DAMD-17-83-C-3018, is with RCA Laboratories, Princeton, NJ for the development of a device which will measure heart rate through protective clothing. The technique used for measuring heart rate is microwave detection, somewhat similar to that being done by the Navy. In the first prototype delivery, the device did not work in the M113, but RCA was attempting to correct this problem. No tests have been made for helicopter use. Twenty-four prototypes are to be delivered by this summer.

The last Army contract, No. DAMD-17-83-C-3019, is with Industrial Biomedical Sensors Corp. of Waltham, MA. This company is using a surface measured cardiac wave detection technique as the indicator of heart beat. The device that is being built is to be a rugged, chemically hardened unit about the size of a hand calculator. A prototype of the device did not operate in the M113, and it has not been tested in a helicopter. Twenty-four additional prototypes are to be delivered as part of this contract.

TEST AND EVALUATION OF MEDICAL EQUIPMENT FOR MILITARY AIRCRAFT USE

MILITARY TEST AND EVALUATION

There are no military specification statements written that cover equipment used in aeromedical evacuation, but procedures for testing do exist and are concentrated with the Air Force. When either the Navy or the Army has a device that needs to be tested for potential aircraft use, the Air Force is requested to perform the test through the official mechanism of the Memorandum of Understanding or Letter of Agreement between either the Navy and the Air Force or the Army and the Air Force. Results of that particular test are provided, and are summarized in the regularly published status report.

AIR FORCE PROCEDURES

The Air Force has the only well developed test and evaluation program for aeromedical evacuation equipment. Their program is run by the Aeromedical Systems Branch, Crew Technology Division, at the School of Aerospace Medicine (USAFSAM/VNC), Brooks AFB, Texas. The personnel in the program include one biomedical engineer, one flight nurse, two aeromedical evacuation techicians, and one biomedical equipment technician.

There are three main functions of the testing program. Their description and the way they are used is as follows:

1) Test and Evaluation - Test and evaluation of medical equipment as requested by Air Force Users. The user sends a request to the 375 AAW/SGNE (Airmedical Airlift Wing), Scott AFB, where it is screened. If approved, it is passed to the Aerospace Medical Division (AMD/RD) at Brooks AFB, which then tasks the USAFSAM/VNC for performance.

2) Research and Development - Research and development of medical equipment when the need cannot be satisfied by the commercial market. Requests for research and development come from HQ MAC/SG at Scott AFB, where a statement of need is forwarded to AFSC (Systems Command) at Andrews AFB, MD. The request is then passed to AMD/RD at Brooks AFB, and finally to USAFSAM/VNC.

3) Technical Support to the Navy and Army - Respond to Navy and Army requests for test and evaluation. Based on Memoranda of Understanding request for the Navy comes from the Naval Medical Research and Development Command in writing to the AMD/RD, Brooks AFB. A request for the Army comes through Ft Sam Houston, USA Medical Department Board, AHS, Attn: HSHA-UBS, Ft Sam Houston, TX.

Through whatever mechanism the Air Force receives the test and evaluation request, they assign a project coordinator within the Aeormedical Systems Branch. That person acts as the point of contact

within the branch, insures that all branch members review operating and maintenance instructions and contractor test data, establishes a time and date for the planning meeting, prepares the test and evaluation protocol, monitors the test progress, and prepares the final test and evaluation report. When possible, the project coordinator also arranges for the loan of the commercial equipment, if that is the objective of the test request.

The Air Force has well developed procedures for test and evaluation, as outlined in the "Test and Evaluation Planning Guide for Aeromedical Equipment," Aeromedical Systems Branch, Crew Technology Division, School of Aerospace Medicine Brooks, AFB, TX, published in August 1982. In this document, they establish uniform methods for test and evaluation of medical equipment to determine suitability for use in the military aeromedical evacuation environment.

Evaluation is concentrated in three areas: general characteristics, physical characteristics, and human factors. In each of these areas the Planning Guide lays down specific evaluation methods based on observation of the equipment and on defined test methods. These definitions include environmental tests of altitude, temperature, and humidity; physical tests of vibration; electrical characteristics tests of electromagnetic interference, leakage current, ground resistance, insulation, and defibrillator waveform. Reference is made to appropriate MIL-STD in the Planning Guide. Procedures and apparatus necessary to perform the tests are also presented.

The Air Force Planning Guide also establishes modified clinical tests when operation of the equipment in the aeromedical evacuation environment is significantly different from that specified by the manufacturer for normal use. This list of tests covers inflight feasibility in the aircraft or helicopter specifically for securing equipment, validity of manufacturers operating instructions, power requirements, onboard storage requirements, and safety of airborne operation.

Since there has been increasing interest in some specialty areas of medical equipment, the Air Force is reworking the planning guide to include test and evaluation of specific generic items, particularly ventilators and vital sign monitors. The result of the latter was described in the introduction to this report.

Another Air Force policy as a result of their test and evaluation program is to publish information on the equipment tested ("Status Report on Medical Materiel Items Test and Evaluated for Use in the USAF Aeromedical Evacuation System," S. L. Oliver, Capt, USAF, NC, and L. A. Warfel, SSgt, USAF, USAFSAM-TR-82-50, December 1982), and to distribute that list to all units that may be involved in aeromedical evacuation. No equipment may be bought specifically for aeromedical evacuation unless it is on the approved list, and medical equipment taken aboard any aeromedical evacuation must be from the approved list. Both of these policies help to assure the safety of the crew and the effectiveness of treatment of the person being evacuated.

NAVY PROCEDURES

The Navy has no established test and evaluation program for medical equipment for use aboard any fixed wing aircraft or helicopter, but relies on the Memorandum of Understanding with the Air Force to provide adequate analysis of appropriate equipment. The general procedures defined in the memorandum are the following:

1. Each organization shall establish requirements or otherwise identify a need for a device prior to initiation of the evaluation process.

2. Specification and/or performance standards shall be agreed upon prior to the evaluation.

3. Joint test and evaluation shall not begin until the evaluation plan has been approved by both organizatons.

4. Generally, modification of the test item will not be permitted during the evaluation. Any modification will require the advance approval of both organizations.

5. Any coordination with the product manufacturer will be accomplished by or through the project coordinator. Joint service reports will not normally be distributed outside service channels.

6. Evaluation reports will be signed by project officers and consultants of each organization. Recommendations, if included, will be identified by the organization in those cases where agreement is not unanimous. Identical reports will normally be forwarded by each organization through their separate channels.

7. Since evaluations are of mutual interest and mutually beneficial, reimbursement, to include travel, will not be required.

8. In addition to the guidelines presented here, both organizations will cooperate in the free exchange of information and/or findings concerning evaluation efforts accomplished by either organization.

9. This Memorandum of Understanding shall be reviewed annually to ascertain its currency, accuracy, and essentiality.

It is through this Memorandum of Understanding that the Air Force is testing two currently manufactured vital sign monitors at the request of the Navy. These units are the Lifestat 100, manufactured by Physio Control, Redmond, WA and the Omega 5000, manufactured by Invivo Research Laboratory, Broken Arrow, OK. Both units use the oscillometric technique, a method which has been successful on a helicopter and on a research unit on the Army M113 Armored Personnel Carrier. The Memorandum of Understanding was sent requesting that the Air Force Planning Guide be followed with the addition of a modification to the humidity test.

The Memorandum of Understanding was first signed between the Navy and the Air Force in January 1977. It has not been used for commercial equipment testing since that time except for the request of this project

for these two specific vital sign monitors.

According to item 8 of the memorandum, the Navy receives copies of the Air Force findings. Their distribution list shows NMRDC, Bethesda, MD and Naval Aerospace Medical R&D, Pensacola, FL receiving copies of test and evaluation reports and status reports. There does not appear to be any policy by the Navy for further distribution of these documents to potential participants in aeromedical evacuation.

Also, there does not appear to be any requirement by the Navy that only approved equipment be purchased and used in aeromedical evacuation. Commercial medical equipment that is now being used in fixed wing aircraft and helicopters may not have been tested for safe and effective use in that environment. This may be a hazard to both the person being evacuated and the aircraft crew.

Lack of distribution of test and evaluation documentation and lack of a safety and effectiveness policy for aeromedical evacuation is a problem for the Navy that should be dealt with soon.

ARMY PROCEDURES

The Army has a Letter of Agreement with the Air Force to cover aeromedical equipment suitability test information and exchange of medical equipment test and evaluation information. The Army agreement is between the Directorate of Medical Equipment Test and Evaluation (DMETE), Academy of Health Sciences, US Army (AHS), Fort Sam Houston, TX and USAFSAM. It covers the following points:

1. Aeromedical equipment suitability tests will be performed:

   a) A letter from DMETE will be provided USAFSAM requesting suitability determination of an item/system for use onboard aeromedical evacuation aircraft.

   b) Based on their standards, USAFSAM will determine acceptability/unacceptability of the item/system and forward to DMETE the test and evaluation results.

2. DMETE will provide to USAFSAM copies of Equipment Inquiry (EI) Reports, or other test reports, as requested.

3. USAFSAM will provide DMETE the annual updated "Status Report on Medical Materiel Items Tested and Evaluated for Use in the USAF Aeromedical Evacuation System."

4. USAFSAM will provide DMETE with a copy of each completed test and evaluation report.

The Army distributes the Air Force test and evaluation reports and the status reports. It also follows the same policies about purchase and use of equipment aboard aeromedical evacuation as does the Air Force.

NATO STANDARDIZATION AGREEMENTS (STANAG)

The majority of the nations participating in NATO have agreed upon standards for the use of terminology, procedures, and equipment in aeromedical evacuation in order to facilitate the transport of patients of one NATO nation in the aircraft of any other NATO nation. Of importance to this report, the standard of agreement deals with general aeromedical evacuation ("Aeromedical Evacuation," STANAG 3204) and covers composition of aeromedical crews, aeromedical crew training, and aeromedical crew equipment. The agreement provides a guide to training which should cover the history of aeromedical evacuations, lectures on effects of flight on health and disease, demonstrations of equipment, flight familiarization, and a number of other things important to care of a casualty in flight. The equipment parts of this agreement, however, are of a nonspecific nature, and neither discuss vital sign monitors or other technology based life support equipment, nor restrict items for safety and effectiveness. This agreement was implemented by the Navy in October 1973. Individual nation participants in NATO are permitted to add reservations to any agreement, and it might be worthwhile to add the restriction to use of US Air Force approved equipment on aeromedical evacuations.

STANAG 2126, "Medical First-Aid Equipment and Supplies," does not discuss vital sign monitors or other life support equipment. No restrictions are placed on the Navy by this NATO agreement.

A third agreement, STANAG 2087, "Medical Employment of Air Transport in Forward Aeromedical Evacuation," covers details for medical use of aircraft in a location where the Navy may use helicopters. This document discusses medical priority in requests for air evacuation, the selection of the sick and wounded, and loading procedures. It does not discuss either specialized training for personnel or safe and effective use of equipment.

NAVY SHIP REQUIREMENT

In the course of looking for a commercial vital sign monitor which would provide diagnostic quality information and survive in the adverse environmental conditions of a helicopter, the environmental requirements placed on medical equipment in the shipboard environment were examined. The Naval Ocean Systems Center has an experienced environmental test organization which is familiar with the military specifications applied to electronic equipment, and has facilities necessary to test or validate compliance with any specification. This group was consulted for information related to the additional limitations placed on all medical equipment by the environment of a ship.

In essence, the major tests outlined in the Air Force Planning Guide for vibration, temperature, altitude, electromagnetic interference, and electrical characteristics meet or exceed the requirements for most of the environmental tests for Navy operations. For shipboard qualification of medical equipment, a number of additional tests should be added as follows:

1) Underwater blast test - Equipment should not be required to survive this test, but would demonstrate that it would not become a hazard to personnel if so exposed. This is a destructive test and may prove expensive for some equipment.

2) Corrosion resistance - Salt spray. Equipment should be put through the salt spray test according to MIL-STD 810C.509.

3) Humidity - The Air Force currently tests to MIL-STD 810C.507.1, which increases humidity to a preset value and then holds it for 6 hours. This should be changed to MIL-STD 810C.507.1-3 procedure IV, which would cycle the humidity five times. This would simulate the humidity change encountered by an aircraft taking off and landing several times in a humid climate. This was requested as a modification to the test of both vital sign monitors being done by the Air Force for the Navy via the Memorandum of Understanding.

The Navy is also instituting a workmanship stress screening test for some equipment. This is not a qualification test, but a test to determine possible weak points in equipment design. The screening covers vibration and thermal cycling and is meant to identify potential failures in the field before they occur so that corrective measures may be taken. Details of the screening program are defined in NAVSEANOTE 3900, 8 February 1984.

NOSC has developed a number of environmental tests that are less rigorous than MIL-STD 810C for communications equipment intended for shipboard use. The tests, called the TELCAM tests, cover vibration and combinations of temperature and humidity. They are chosen to represent the usual conditions existing aboard a ship and do not cover the environment that may exist after a ship has suffered a fire or broken steam line, after it has sustained battle damage and can no longer control temperature and humidity, or when spaces are uninhabited and temperatures are unintentionally uncontrolled.

In the TELCAM tests, the equipment is exposed to vibrations from approximately 4 Hz to 60 Hz, with a range of amplitudes necessary to identify resonances. For temperature and humidity, the equipment is exposed to temperatures from 20° C to 50° C with a relative humidity range of 68 to 95%. The equipment is cycled through combinations of temperatures and humidities for a five day period. Details for the TELCAM testing can be obtained from the NOSC Environmental Test Branch, Code 943.

AEROMEDICAL EVACUATION PERSONNEL TRAINING

Both the Army and the Air Force participate in the Military Assistance to Safety and Traffic (MAST) program. This program was initiated in 1969 by the National Highway Traffic Safety Bureau to use military helicopters to assist highway accident victims. After an initial study, it became apparent that assistance should not be limited to just highway accidents, and the program was expanded to include all serious medical emergency situations.

The decision by the military to participate provides advantages to both the civilian and military communities. The benefit to the civilian community is obvious, in that highly trained personnel and advanced equipment are available to respond to medical emergencies requiring either search and rescue or transport. Participation in actual civilian rescue and transport missions provides military aeromedical evacuation crew members with better training than could be realized from simulated exercises. Furthermore, current medical equipment and supplies can be maintained in a state of readiness to support military rescue and evacuation missions.

The MAST program has had considerable success since its beginning. As of 1982, there were 31 active MAST units. All were either Air Force or Army.

In October 1982, a Tri-Service Aeromedical Research Panel Technical Meeting was hosted by the US Army Aeromedical Research Laboratory, Fort Rucker, Alabama. The Navy, Air Force, and Army discussed their programs for training and equipment during aeromedical evacuations. The Air Force conducts training in the management of patients on both tactical and strategic air evacuation systems. The course, conducted at USAFSAM, uses a number of ground-based simulators for providing realistic training during aeromedical evacuation. The material covers the stresses of flight, limitations of the aircraft environment, how to provide continuity of care within a confined space, decision-making techniques, and teamwork. This course is offered to both flight nurses and aeromedical technicians.

The Air Force Aerospace Rescue and Recovery Service Regulation on Emergency Medical Treatment (ARRSR 160-34) contains one chapter on aeromedical evacuation. This chapter covers medical hazards of air evacuation, loading, securing and transporting of patients, and considerations for specific medical circumstances.

Both the Air Force and the Army dedicate helicopters to aeromedical purposes, so training of personnel and maintenance equipment must be kept at a high level. The seagoing Navy, on the other hand, does not dedicate resources, either aircraft or personnel, for medical purposes. There are no dedicated search and rescue teams for locating and treating downed

aircrews. A rescue swimmer may lose a potential survivor through inadequate training or equipment when faced with a critical medical emergency. For medical evacuation at sea, aircraft and aircrews are diverted from the primary mission for which they were trained. There are no standardized procedures, equipment, or training for medical evacuation by helicopter between ships at sea.

OTHER TEST AND EVALUATION SERVICES

A medical devices evaluation organization was identified which tests both the safety and effectiveness of classes of commercial medical devices. This organization, Emergency Care Research Institute (ECRI) of Philadelphia, PA, tests a full range of medical equipment when numerous manufacturers are represented in a single product. They test purely mechanical items like Gurneys and carts and high technology items like defibrillator/monitors and vital sign monitors. Their tests cover conditions that are expected in a civilian hospital, and are not inclusive for conditions of aeromedical evacuation or shipboard use. Their tests do, however, provide a starting point from which the Air Force proceeds for their Planning Guide tests. In addition, ECRI rates the effectiveness of a piece of equipment in doing its designed for task. This information, not provided by the Air Force, should be of use to all military medical equipment purchasers, including land based hospitals, shipboard medical departments, and aeromedical evacuation services. The ECRI information is available through a periodical publication called Health Devices, and should be provided to all persons involved with the purchase of medical equipment.

SUMMARY

As a general rule for military medical purposes, it is less expensive to use commercial equipment than to develop new specialized devices. Often, however, commercial products do not meet some of the special requirements of military applications. Use of vital sign monitors aboard the high noise and vibration environment of helicopters is one example of a specific requirement. To determine how close current products meet needs, a survey was made of commercial vital sign monitors with potential use in a helicopter (total number in survey was 15). Manufacturers were consulted about performance specifications. None specifically addressed helicopter use.

The Air Force shares the same concerns about casualty care, and up to December 1982 their well developed program for test and evaluation of equipment for aeromedical evacuation had found one commercial vital sign monitor currently in production that is suitable for use in a helicopter. This unit is the Medtek BPI 420 Blood Pressure Instrument (Quest Medical Corp., Dallas, TX). This unit is a small, portable instrument that can be hand held or mounted to a desktop or wall. It can be powered by either battery or 115/230 VAC 50-400 Hz. It measures systolic and diastolic arterial pressure as well as pulse rate. It uses the oscillometric technique in conjunction with a microprocessor. The BPI 420 uses a standard adult-size cuff system with Velcro fasteners, inflation bladder, and bulb. It does not automatically and periodically inflate the cuff, but once hand inflated, cuff deflation is automatically controlled at a rate of 2.3 mm Hg/sec. This unit automatically calibrates itself to the ambient barometric pressure from 1200 ft (366m) below sea level to 30,000 ft (9,146 m) above sea level. Operator errors or unit malfunctions are displayed on the front screen with the probable cause.

A second unit identified, the Biomega Blood Pressure/Pulse Monitor, Model 423B (Biomega Corp, Gainesville, FL), is no longer made.

It has been reported that the Israel Defense Force has a device for life support use aboard helicopters. This device includes measurement of vital signs. Their equipment is being developed for commercial use and is proprietary at this time. Inquiries about it have produced no detailed information.

Since new special purpose products are often developed under the sponsorship of the military, the Air Force and Army were consulted about their research efforts. Contracts are in progress to develop specialized vital sign monitoring devices for use through protective clothing, for measurement of heart rate at a distance, and for use on the Army M113 armored personnel carrier. No device from these contracts is in production yet. The testing of one prototype blood pressure monitor for measurement through protective clothing during transport on an M113 was observed. The device tested was marginally successful. However, it has potential for helicopter use should it be put into production for the M113.

At present, the Air Force has the only established program for test and evaluation of medical equipment for aircraft use. The program is run

through the USAF School of Aerospace Medicine (USAFSAM) at Brooks AFB, Texas. They test for use aboard both fixed wing aircraft and helicopters. Reports are prepared for each item tested, and a status report is published summarizing all the items tested. Both the Navy and the Army have Memoranda of Understanding through which each can request that the Air Force test some specific medical equipment.

Through the Memorandum of Understanding with the Navy, the USAF School of Aerospace Medicine was asked to test two new vital sign monitors whose manufacturers specifications showed potential for successful helicopter use. These are the Lifestat Model 100 (Physio Control, Redmond, WA) and the Omega 5000 (Invivo Research Laboratory, Broken Arrow, OK). The report on these devices will be published by the USAFSAM when completed.

A commercial medical equipment testing service that deals with general safety and function were discovered which could be useful to both the Fleet and the Navy hospital system. This is the publication, Health Devices, by Emergency Care Research Institute. This publication presents a careful analysis of safety and effectiveness of individual pieces of medical equipment from a class. It is used by the Air Force as a reference to much of their test, evaluation, and consulting.

The Air Force follows through on test and evaluation of medical equipment by informing pilots about which devices are approved for aeromedical evacuation and by requiring that pilots allow only approved devices on board. The Air Force also specially trains their aeromedical evacuation personnel in the use of the equipment.

Out of this investigation, information was obtained about medical equipment compatibility with Navy ship requirements and about potential test and evaluation procedures for shipboard compatibility.

Finally, NATO Standardization Agreements were found which relate to aeromedical evacuations. The agreements do not cover effectiveness and safety of any life support equipment and ,therefore, do not affect vital sign monitors selected as a result of this investigation. However, they do address training and qualification of aeromedical evacuation personnel.

RECOMMENDATIONS

1. Provide the Air Force list of equipment currently approved for fixed wing aircraft and helicopters, as well as updates, to all potential land and sea units which may participate in medical evacuations. For the safety of the patient and the crew, limit use of medical equipment to the approved items.

2. Establish a training program or include a section in the Corps school that covers aeromedical evacuation. The training should be compatible with NATO instruction and qualification. The special circumstances covered should include problems that can arise from measurement and treatment at altitude variations and in noise and vibration. Much can be learned from the Army air ambulance service, the Military Assistance to Safety and Traffic (MAST) program, and civilian lifeflight and air ambulances.

3. Continue to use the Memorandum of Agreement with the Air Force for testing medical equipment for aircraft use. Establish a supplemental facility or procedure for additional tests for shipboard use when not covered by the Air Force test and evaluation procedures.

4. Screen all equipment purchased by the Navy for possible use on aircraft or aboard ship against the approved list and in compliance with environmental test standards. Inform all potential suppliers of these requirements so that they may include these considerations in their manufacturing process.

5. Revise Authorized Medical Allowance List (AMAL) to indicate fixed wing aircraft and helicopter approved equipment. Label all equipment approved for aeromedical evacuation. Phase out all equipment not meeting environmental test standards for shipboard use.

6. Inform all medical equipment users of the publication, Health Devices, by Emergency Care Research Institute.

APPENDIX A: VITAL SIGN MONITORS

Company and Model	Physio Control VSM-2	Physio Control Lifestat 100	Physio Control Lifestat 200
Address	Redmond, WA	Redmond, WA	Redmond, WA
Technique	Oscillometric	Oscillometric	Oscillometric
Vital Signs Measured	Systolic Diastolic Mean Rate Temperature ECG	Systolic Diastolic Mean Rate	Systolic Diastolic Mean Rate
Operating Mode	Auto Inflate Manual Inflate Auto Deflate	Auto Inflate Manual Inflate Auto Deflate Timed Cycle	Auto Inflate Manual Inflate Auto Deflate Timed Cycle
Display		LED	LED Printer Time Cuff Pressure
Power	Line Nicad Battery	Line Lead Acid Battery	Line Nicad Battery
Battery Life	30 min	2 hr	2 hr
Charge Time	16 hr	16 hr	
Weight (lbs)	25	18	15
Size (WxHxD) (inches)	12x7.75x11.25	8x3.5x11.5	6x9x11.5
Special Features	Alarm on pressure (sys,dia,mean) Alarm on rate RS232 output		Alarm on pressure (sys,dia)

Company and Model	Puritan Bennet D4001	Paramed-Technol Cardivan 9200	Medtek BPI 420
Address	Kansas City, MO	Palo Alto, CA	Princeton, NJ
Technique	Ultrasound	Pressure Sense	Oscillometric
Vital Signs Measured	Systolic Diastolic Rate	Systolic Diastolic Mean Rate	Systolic Diastolic Mean Rate
Operating Mode	Auto Inflate Auto Deflate Manual Inflate Timed Cycle	Auto Inflate Auto Deflate Manual Inflate Timed Cycle	 Auto Deflate Manual Inflate
Display	LED	LED	
Power	Line		Line Battery
Battery Life			
Charge Time			
Weight (lbs)		13	
Size (WxHxD) (inches)		6.5x8x12	
Special Features		Alarm on pressure (sys,dia) Alarm on rate	

Company and Model	AirShields Noninvasive BP Monitor	Invivo Research Omega 5000	Invivo Research Omega 1000
Address		Broken Arrow,OK	Broken Arrow, OK
Technique	Oscillometric	Oscillometric	Oscillometric
Vital Signs Measured	Systolic Diastolic Mean Rate	Systolic Diastolic Mean Rate Temperature	Systolic Diastolic Mean Rate
Operating Mode	Auto Inflate Auto Deflate	Auto Inflate Auto Deflate	Auto Inflate Auto Deflate
		Timed Cycle	
Display	LED Printer Time Cuff Pressure Trends	LCD Printer Time Cuff Pressure Trends	LED Printer
Power	Line	Gel Battery	Line
Battery Life		6 hr	
Charge Time		1.2 hr	
Weight (lbs)	20	14.6	13.75
Size (WxHxD) (inches)	13x8x10	9.5x4.25x10	12.75x11.9x4.75
Special Features	Alarm on pressure (sys,mean) ASCII output	Alarm on pressure (sys, mean)	Alarm on pressure (sys)

Company and Model	Datascope Accutorr I	Datascope Accutorr 2	Critikon Dinamap 1846
Address	Paramus, NJ	Paramus, NJ	Tampa, FL
Technique	Oscillometric		Oscillometric
Vital Signs Measured	Systolic Diastolic Mean Rate		Systolic Diastolic Mean Rate
Operating Mode	Auto Inflate Auto Deflate	Auto Inflate Auto Deflate	Auto Inflate Auto Deflate
	Timed Cycle	Timed Cycle	Timed Cycle
Display	LED Printer Time	LED	LED
Power	Line	Line	Line
Battery Life Charge Time			
Weight (lbs)	19	12	
Size (WxHxD) (inches)	12x5.6.4.25	8x5.6x11.25	
Special Features	Alarm on pressure (sys)	Alarm on pressure (sys)	Alarm on pressure (sys,dia)

Company and Model	Somatronix Medipulse-313	Cardiodyne PV-100	IBS Corp SD-700A
Address	Bristol, CT	Los Gatos, CA	Waltham, Mass
Technique	Auscultatory	Auscultatory	Auscultatory mod
Vital Signs Measured	Systolic Diastolic Rate	Systolic Diastolic Mean Rate	Systolic Diastolic Rate (optical)
Operating Mode	Auto Inflate Auto Deflate		Auto Inflate Auto Deflate Timed Cycle
Display	LCD Printer		LED
Power	Line 4-"c" Cells	Line	Line Recharge Battery
Battery Life Charge Time			
Weight (lbs)	2		10.5
Size (WxHxD) (inches)	6x3x6		9.3x7.8x8.8
Special Features			Alarm on rate

APPENDIX B: MONITORS TESTED BY THE ARMY IN APRIL 1982

INSTRUMENT AND MANUFACTURER	CHARACTERISTICS
Hemosonde Model 2300 Park-Davis and Company Waltham, MA	Ultrasonic technique Manual inflation and deflation Analog display Blood pressure only
Biomega 423A Biomega Corp.	Oscillometric technique Manual inflation, auto deflation LED digital display Battery powered Blood pressure and heart rate
BPI 420 Medtek Corp Princeton, NJ	Oscilometric technique Manual inflation, auto deflation LED digital display Battery powered Blood pressure and heart rate
Somatronix Model 307 Somatronix Research Corp Bristol, CT	Auscultatory technique Manual inflation, auto deflation LED digital display Battery powered Blood pressure and heart rate
Vita-stat Model 900S Vita-stat Medical Services, Inc St. Petersburg, FL	Ascultatory and oscillometric technique Automatic inflation and deflation LED digital display AC powered Blood pressure and heart rate
Dinamap 845 Critikon, Inc Tampa, FL	Oscillometric techique Automatic inflation and deflation LED digital display AC powered Blood pressure and heart rate
Roche Arteriosonde 1225 Kontron, Inc Everett, MA	Ultrasonic technique Automatic inflation and deflation LED digital display AC powered Blood pressure and heart rate

APPENDIX C: NAVY DISTRIBUTION LIST FOR AIR FORCE MEDICAL TEST AND EVALUATION AND STATUS REPORT

Naval Aerospace Medical Research and Development Center
Pensacola, FL 32508

Naval Medical Research and Development Command
Bldg 142
National Naval Medical Center
Bethesda, MD 20014

APPENDIX D: BIBLIOGRAPHY AND RELATED DOCUMENTS

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